1 530 324

# PATENT SPECIFICATION

(11) 1 530 324

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(19)


## (54) CATHETER INSERTION DEVICE

(71) We, TRAVENOL LABORATORIES INC., a Corporation organised and existing under the laws of the State of Kentucky, United States of America, of 200 Baxter Parkway, Deerfield, Lake County, Illinois, United States of America, do hereby declare the invention for which we pray that a Patent may be granted to us and the method by which it is to be performed to be particularly described in and by the following statement:—

This invention relates to a device for the insertion of a catheter into the vascular system of a patient, and more particularly to such devices of the type which employ a dispenser having a rotatable catheter receptacle to forward the catheter through a needle, which is secured, in use, to the dispenser.

Dispensing devices employing a rotating receptacle action similar to that disclosed in this specification have been known in the prior art (e.g. U.S. Patents 2,685,097 and 3,561,445) and the present invention provides an improvement over this prior art.

The present invention provides a catheter insertion device comprising a base having a catheter outlet, spindle integral with the base extending from a central portion of the base; a generally cylindrical catheter receptacle having a top wall with a central aperture rotatably engaging the spindle so that the end of the receptacle opposite such top wall rotatably confronts the base and the spindle extends through the top wall; and a catheter wound inside the cylindrical wall of the receptacle and extending through the outlet, whereby the catheter may be forwarded through the outlet into the body of a patient by rotation of the receptacle and the receptacle may be subsequently removed from the base with one hand from above the base by digital pressure on the end of the spindle accompanied by an upward pulling force on the cylindrical wall of the receptacle in the direction away from the base.

The advantages of the device described hereafter are most marked with regard to applications in which relatively long catheters are required. An example of such a situation is the introduction of a catheter to forward the distal end thereof to the central veins of the chest, through an entry made in the peripheral vessels, such as those in the arm. Such an application may require as much as a twenty-four inch catheter length. The utilization of the device disclosed herein represents a significant stride forward in the emplacing of such catheters. The device may also be used with medium length and long catheters smaller than twenty-four inches, particularly those over about eight inches.

The device disclosed herein is particularly advantageous in connection with the incorporation of catheters formed from silicone elastomer tubing. The desirable properties of silicone elastomer tubing for use in catheters for intravenous infusion of fluids or other medical applications have been known for over twenty-five years. The materials from which tubing of this type are fabricated, for example, a silicone elastomer marketed under the trade mark "SILASTIC", are marked by a high degree of body compatibility compared with other materials from which catheters have been and are formed, such as polyethylene, polytetrafluorethylene, and vinyyl polymers. The silicone elastomers are relatively inert to organic tissues and fluids, non-clotting as to the blood and are highly flexible so as to reduce the trauma involved in their insertion and maintenance in the body. It is possible to maintain a silicone elastomer catheter implanted in the body for a longer period of time than with other types of tubing. The necessity for frequent removal and reintroduction of catheters is a marked disadvantage in almost any medical application.

One particular difficulty experienced in the past with respect to inserting and forwarding relatively long silicone elastomer catheters has been the difficulty in providing sufficient stiffness and control over the catheter during forwarding while avoiding

FIGURE 16 is a view showing the step of completing the catheter insertion prior to removal of the needle.

The catheter insertion device illustrated includes a catheter dispenser generally indicated by the reference numeral 10 secured to a slotted needle 12. Dispenser 10 is formed by the releasable engagement of a catheter receptacle 14 and a base 16.

The catheter receptacle 14, which may be fabricated as an integrally molded plastics member, comprises a cylinder defined by a circumferential outer wall 18. A flat top wall 20 extends across one end of cylindrical wall 18. A central mounting aperture 22 is formed in top wall 20. In addition, a pair of offset apertures 24 and 26 are provided in top wall 20. Receptacle 14 is provided with an inner cylindrical wall 28 extending axially from top wall 20, defining an annular space 30 between outer receptacle wall 18 and the inner wall 28. The thickness of wall 28 is increased at the top of space 30 to reduce the width of space 30 at its juncture with top wall 20. The cylinder formed by wall 28 is not complete, but is provided with a gap 32 which provides a means for passage between the central area of receptacle 14 encompassed by inner wall 28 and the annular space 30 through which a catheter may be passed. A catheter hub restraining wall 34 extends radially inwardly from inner wall 28 near the gap 32. A catheter hub restraining post 36, complementing wall 34, is spaced from wall 34 so that a catheter hub may be placed between restraining wall 34 and post 36.

At the lower end of receptacle 14, outer wall 18 is provided with an outwardly turned bearing lip or flange 38 for engagement with the base 16.

Base 16, which may likewise be fabricated as an integrally molded plastics article, has as its major portion a flat plate 40 in the shape of a circle. Plate 40 is provided with a circumferential upper flange 42 and lower flange 44 at the intersection of a cylinder 46 with the periphery of base plate 40.

Needle hub 50 is formed integrally on the outside of cylinder 46, and is provided with a longitudinal slot 52 running the entire length of needle hub 50. Cylinder 46 has a catheter outlet slot 53 which communicates with the longitudinal slot 52 of needle hub 50. In combination, the needle hub slot 52 and outlet slot 53 provide a channel communicating from the interior of base 16 encompassed by cylinder 46 with the outer end of needle hub 50. Base plate 40 is provided with a channel or guide depression 54 formed circumferentially in its surface leading into outlet slot 53.

Hollow slotted needle 12 is provided with a pointed distal tip 56 suitable for piercing and a longitudinal slot 58 running its entire length. Needle 12 is secured to needle hub 50 so that needle slot 58 is registered with the slot 52 of needle hub 50. Needle 12 may be secured to hub 50 by any convenient means, such as by molding or a tab-in-groove lock. There is thus provided a channel for moving a catheter from the interior of base 16 to the distal point 56 of needle 12, with a continuous slot providing access to that channel by the catheter outlet slot 53, needle hub slot 52 and needle slot 58.

A mounting spindle 60 is formed integrally on the central portion of base plate 40. Mounting spindle 60 extends axially upward from base plate 40 and its upper portion is trifurcated by longitudinally extending slots 62 to form three yieldable spindle fingers 64 as the upper portion of spindle 60. A detent bead 65 is formed on spindle 60 circumferentially around the fingers 64 near the top of spindle 60.

Spindle 60 cooperates with mounting aperture 22 on receptacle 18 to secure receptacle 18 to base 16 in rotating engagement. Spindle 60 extends upwardly through the aperture 22 in top wall 20 of receptacle 18 so that the detent bead 65 restrains top wall 20 and the top end 68 of spindle 60 extends above the receptacle 18. In this position, the receptacle mounting flange 38 slidingly confronts the periphery of plate 40 on base 16. So mounted, the base 16 and receptacle 18 form the dispenser 10 and the receptacle 18 may be rotated with respect to base 16.

Spindle 60 is hollow throughout its length and receives a release button shaft 66 having a release button 67 formed integrally at the top thereof. Release button 67 is secured in position over the top of fingers 64, as illustrated in Figures 2 and 3. A mounting stop 68 formed on the bottom of shaft 66 as it extends through base plate 40 prevents upward movement of shaft 66 within the spindle 60. Release button 67 has an inner frustoconical surface 69. On depression of button 67, the surface 69 acts to press the fingers 64 inwardly together to assist in disengaging head 65 from receptacle 18.

Base 16 is provided with a guide mounting aperture 70 through the periphery of plate 40 near the catheter outlet slot 53. Catheter guide means in the form of an elongate flexible guide rod 72 extends upwardly from plate 40 through aperture 70. Guide rod 72 may be in the form of a thin solid rod formed from some relatively stiff but still yieldable and flexible material such as polyethylene or nylon. The lower end of guide 72 is flat so as to provide a convenient mounting plate 74. As illustrated in Figures 5 and 6, the guide 72 may be secured to base 40 on the underside of base 40 by means of pegs 76 integrally formed on the underside of base 40 adjacent the aperture 70.

receptacle 18, progressively less of the catheter 80 remains above the guide 72. When only one turn of catheter 80 remains in receptacle 14, no portion of catheter 80 remains above the guide 72 to restrain the free end 79 of the guide 72 from its natural bias upwards. Since the guide 72 extends upward from base 16 at an angle which would cause the free end 79 when unrestrained to stand as high as the receptacle, free end 79 rides directly to the top of annular space 30 adjacent top wall 20. In such position, an automatic stop 112 is provided by the wall 28 at its edge forming the gap 32. Stop 112 is provided at that edge by the thickened portion at the top of wall 28. Once only the last turn of the catheter remains on the receptacle 14, and the receptacle 14 is rotated to the position illustrated in Figure 14, stop 112 engages guide 72 to positively stop rotation of the receptacle 14 with respect to base 16. This prevents over-running of the end of catheter 80 past outlet 50, which could deform the catheter 80 and stiffener 82 by kinking them at the outlet 50.

During the forwarding operation, combination of the helical stiffener and silicone elastomer catheter together with the rotating dispenser forwarding mechanism and slotted needle cooperates to maximize the opportunity for successful catheter placement. The guide assists in the smooth control of the catheter.

The rotating dispenser enables the user to exercise careful control over the forwarding process. The use of the helical stiffener and elastomeric tubing with such well-controlled forwarding improves the negotiation of long and sometimes tortuous vessels with the delicate catheter while reducing the risk of trauma. It appears that the helical stiffener leads the silicone elastomer catheter through the vein as the dispenser is reeled forward.

While reversal of the dispenser rotation might otherwise risk grave danger of catheter shearing, the use of the slotted needle in the combination reduces the risk from the level which it otherwise might reach with the use of a delicate silicone elastomer catheter.

Once the receptacle has been rotated to the position illustrated in Figure 14, receptacle 14 may be snapped off base 16 as illustrated in Figure 15. The arrangement of the spindle 60 which holds dispenser 10 together permits this removal operation by engagement of the side walls 18 of receptacle 14 with the thumb and middle finger to pull upward on receptacle 14 while the forefinger presses down on the button 67 to assist release of the receptacle 18 from the detent bead 65. This separation operation is thus performed without need to reach a hand or any part thereof underneath base 16, a movement which could cause the base to be tipped up from the skin of the patient possibly causing additional trauma and bleeding. The receptacle 14 may thereafter be discarded.

If desired, the additional length of catheter remaining outside the body may be forwarded into the body in the manner illustrated in Figure 16, by gripping the catheter hub 84 and forwarding the catheter guided by needle 12. Needle 12 can thereafter be removed and the needle 12 with attached base 16 discarded, leaving the catheter in position with the hub ready to be taped or sutured down to the skin of the patient in the conventional manner.

The dispenser 10 disclosed in this application may also be used without attachment of needle 12. In such form, the hub 50 can be mated with any suitable fitting to forward a catheter 80 from the dispenser 10 through such fitting. For example, such use could be made of dispenser 10 with needle 12 omitted in a catheter-through-catheter (CTC) insertion. In such a procedure, an initial insertion using conventional techniques is made to introduce a guide catheter. The proximal end of the guide catheter may be provided with a suitable Luer fitting to receive hub 50 of dispenser 10, whereupon a smaller principal catheter 80 may be introduced from dispenser 10 through the guide catheter.

WHAT WE CLAIM IS:—

1. A catheter insertion device comprising a base having a catheter outlet, a spindle integral with the base extending from a central portion of the base along an axis perpendicular to the major portion of the base; a generally cylindrical catheter receptacle having a top wall with a central aperture rotatably engaging the spindle so that the end of the receptacle opposite such top wall rotatably confronts the base and the spindle extends through the top wall; and a catheter wound inside the cylindrical wall of the receptacle and extending through the outlet, whereby the catheter may be forwarded through the outlet into the body of a patient by rotation of the receptacle and the receptacle may be subsequently removed from the base with one hand from above the base by digital pressure on the end of the spindle accompanied by an upward pulling force on the cylindrical wall of the receptacle in the direction away from the base.

2. A catheter insertion device according to Claim 1, including a hollow needle secured to the catheter outlet, whereby, in use, the catheter is forwarded through the needle.

3. A catheter insertion device according

1530324 COMPLETE SPECIFICATION
4 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

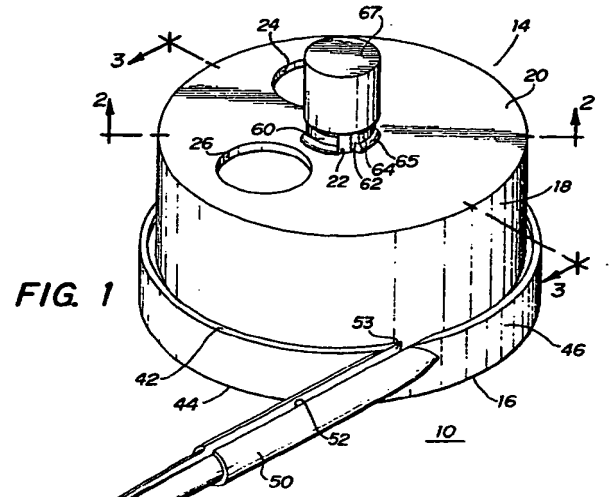


FIG. 1

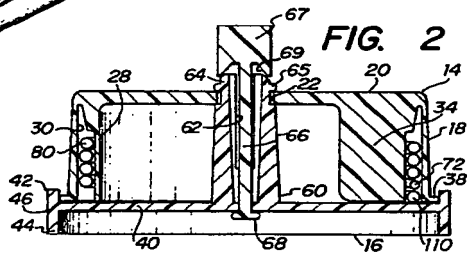


FIG. 2

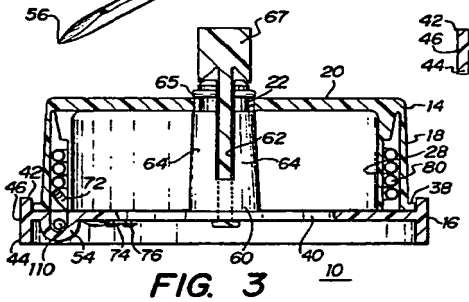


FIG. 3




FIG. 4

1530324 COMPLETE SPECIFICATION
4 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 3

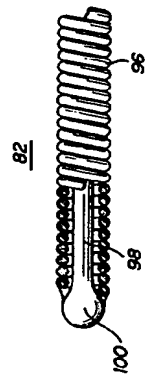


FIG. 11

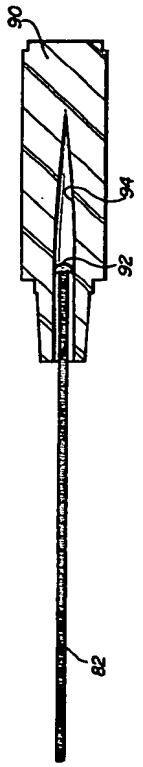


FIG. 12

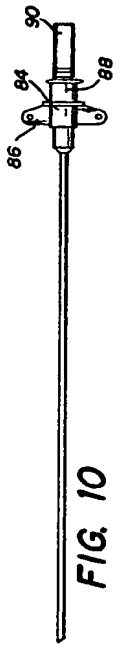


FIG. 10

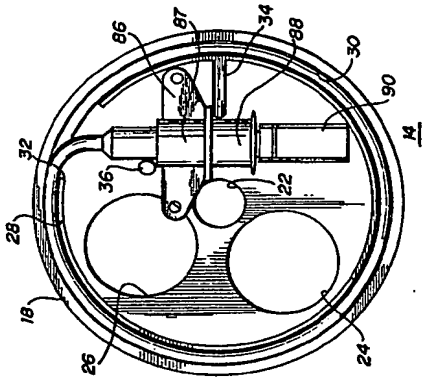


FIG. 9